VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 02/10/09

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Norman Ward, M.D.
Lynne Vezina, R.Ph.
Cheryl Gibson, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Susan Besio, Ph.D., OVHA
Erin Cody, M.D., OVHA
Stacey Baker, OVHA
Cynthia Laware, OVHA
Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA
Judy Jamieson, OVHA

Guests:

Amy Finn, Merck
Carl Marchand, AstraZeneca
Carl Pepe, GSK
Frank Chila, Gilead
Gary Prevost, PriCara
James McGrory, UCB, Inc.
Jenifer Buttle, Merck
Laura Sinofsy-Bohn, AstraZeneca
Matt Badalucco, Merck
Michael Deorsey, Abbott
Pamela DiPerrio, GSK
Paul Kelly, Janssen
Shannon Partenza, Takeda
Terry Lee, Gilead Sciences
Tony Miguel, PG

Michael Scovner, M.D. Chair, called the meeting to order at 7:06 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The January 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- New OVHA Director: Susan Besio, Ph.D., the new Director of OVHA was introduced. The state budget issues were summarized and proposed strategies to make OVHA programs more sustainable were discussed**.** The Medicaid budget book is available on the OVHA website and includes the pharmacy best practices and cost containment report.
- Subutex®/Suboxone® Use: A draft letter to prescribers urging caution in the prescribing of Subutex® prepared by Dr. Scovner was shared with the DUR Board.

4. Medical Director Update: *Erin Cody, M.D., OVHA*

- Clinical Programs Update: No updates to report.

- Prescriber Comments: No comments to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Anti-psychotics: Atypicals and Combinations (Seroquel XR®)
  Deferred until next meeting.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Astepro® (azelastine hydrochlorid) Nasal Spray: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication for the requested medication is allergic rhinitis AND the patient has had a documented side effect, allergy, or treatment failure to loratadine (OTC) OR cetirizine (OTC) AND a preferred nasal glucocorticoid. Additionally, a quantity limit of 1 bottle/25 days was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Keppra XR® (levetiracetam extended-release) Tablet: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has been unable to be compliant with or tolerate twice daily dosing of Keppra IR®.

Public Comment: James McGrory, UCB, Inc. - Commented on the use of Keppra XR® in epilepsy.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Stavzor® (valproic acid delayed release) Capsule: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has been started and stabilized on the requested medication OR the patient has had a documented intolerance to Depakote®.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Urinary Antispasmodics:
  Deferred until next month.

8. Drug Classes – Annual Review:
(Public comment prior to Board action)

Cardiovascular Agents

- Coronary Vasodilators/Antianginals: Nitrates and Nitrites and Ranexa® (ranolazine)
  It was recommended that the criteria for Ranexa® be updated to reflect new labeling. It was also recommended that prescribing for this drug be limited to cardiologists. Nitrogard® Buccal was removed from the table as it is no longer available.

Public Comment: No public comment.

Board Decision: The Board approved the updated criteria for Ranexa® but did not want to limit prescribing to cardiologists.

- Lipotropics: Bile Acid Sequestrants
  No changes were recommended other than changing the length of authorization from lifetime to 3 years.

Public Comment: No public comment.

Board Decision: The Board approved changing the length of authorization.

- Lipotropics: Fibric Acid Derivatives
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged. The Board requested that net pricing comparisons be presented at a later meeting.

- Lipotropics: Niacin
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

- Lipotropics: Statins
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

- Lipotropics: Miscellaneous/Combinations
  No changes were recommended to the current approval criteria.

Public Comment: Rozina Fisher, GSK – Commented on the role of Lovaza® in treating elevated triglyceride levels and its safety and efficacy.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

Gastrointestinal Agents

- Histamine-2 Receptor Antagonists
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged. The Board requested some follow-up information on utilization of cimetidine and drug interactions with this drug.

- Inflammatory Bowel Agents
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

- Proton Pump Inhibitors: Single/Combo
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

Anti-emetics

- 5-HT3 Antagonists
  No changes were recommended to the preferred drugs. It was recommended that in hyperemesis gravadarum, the current criteria requiring a trial of one other anti-emetic be deleted.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- NK1 Antagonists
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

- Anti-emetics: Other
  No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Provigil® (modafinil): Due to the numerous potential off-label uses of Provigil®, a retrospective drug utilization analysis was performed in January 2009 to review utilization and to evaluate the appropriateness of current prior authorization (PA) procedures. OVHA Provigil claims from 1/1/08 to 12/31/08 were reviewed. The information collected included unique members, number of claims, average cost per claim, and plan cost. In addition, a review of prior authorization requests for Provigil® from January 1, 2008 through December 31, 2008 was conducted. The requests were reviewed to determine if the current OVHA authorization procedures for Provigil® are appropriate. Sixteen approvals (15%) and six denials (17%) for a total 22 of 143 PA requests were reviewed. Based on the utilization data provided from January 1, 2008 to December 31, 2008, the average cost per prescription and monthly plan costs have increased but the number of unique utilizers and paid claims have been relatively consistent. There were between three and seven patients in a given month that received 600 to 900 mg of Provigil® daily and had paid claims for Provigil® greater than $1,000. Quantity limits on Provigil® 100 mg tablets can be considered for patients requiring doses greater than 150 mg daily. Based on OVHA's current approval criteria for Provigil®, all the prior authorizations reviewed were appropriately processed.

Public Comment: No public comment.

Board Decision: The Board approved implementing quantity limits for both the 100 mg (dose consolidation) and 200 mg tablets with an upper daily maximum dose of 400 mg.

10. New Drug Product Plan Exclusions: (Consent Agenda Item): *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 12/27/08 - 01/17/09. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*
FDA Safety Alerts

Bisphosphonates – atrial fibrillation

- The FDA issued an update to the Agency's review of safety data regarding the potential increased risk of atrial fibrillation in patients treated with a bisphosphonate drug. Across all studies, no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed. Additionally, increasing dose or duration of bisphosphonate therapy was not associated with an increase rate of atrial fibrillation. Healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

Topical Anesthetics – adverse effects when applied to large areas

- The FDA issued a public health advisory to remind patients, healthcare professionals, and caregivers about potentially serious hazards of using skin numbing products, also known as topical anesthetics, for relieving pain from mammography and other medical tests and conditions. FDA is concerned about the potential for these products to cause serious, life-threatening adverse effects, such as irregular heartbeat, seizures, breathing difficulties, coma and even death, when applied to a large area of skin or when the area of application is covered. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

Plavix® - genetic factors, drug interactions and effect on efficacy

- The FDA notified healthcare professionals that the makers of Plavix have agreed to work with FDA to conduct studies to obtain additional information that will allow a better understanding and characterization of the effects of genetic factors and other drugs (especially the proton pump inhibitors (PPIs)) on the effectiveness of clopidogrel. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 8:36 p.m.

Next DUR Board Meeting
Tuesday, March 10, 2009
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.